

TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Economic Impact Statement

LSA Document #06-425

Description of the Rule

The Executive Board of the Indiana State Department of Health approved preliminary promulgation of an amendment the Communicable Disease Reporting Rule, 410 IAC 1-2.3, to include the reporting of laboratory-confirmed influenza deaths. The proposed amendment requires each physician licensed under IC 25-22.5, and each administrator of a hospital licensed under IC 16-21 or the administrator's representative, to report laboratory-confirmed influenza deaths to the local health officer within 72 hours of first knowledge of death. The amendment also removes the requirement for laboratory confirmation of influenza for those cases of influenza diagnosed based on clinical presentation during an influenza pandemic. Physicians and hospital administrators, or administrators' representatives, are requested to use State Form 52576 (02-06), Influenza-Associated Deaths Case Investigation, to report influenza deaths. This rule amendment is statutorily authorized under IC 16-19-3-4 and IC 16-41-1-2.

The CDC reports that 36,000 Americans die every year from influenza. Based on census data, Indiana's influenza disease burden should be 600 deaths each year. Currently, influenza deaths are extracted exclusively from death certificates. Because of the delay of filing death reports, and the current method of counting these data, the ISDH data is usually unavailable for 1 ½-2 years. The most current information that on influenza deaths is from 2004. Between the years 2002-2004, there were only a total of 101 deaths reported on death certificates. Estimates using the CDC's FluSurge software estimates between 2,365-6,916 excess deaths in Indiana due to influenza pandemic. This estimate is assuming that the attack rate is 25%. Higher or lower attack rates and virulence of the pandemic will affect the excess deaths. The most likely scenario is 4,110 excess deaths.

This rule provides the foundation necessary to monitor the virulence of influenza strains circulating in Indiana. Additionally, it has the potential to save Indiana citizens' lives by providing much needed epidemiological data as evidence to implement appropriate infection control and other response measures. The current method is limited in its ability to provide death data and hinders the ability to make quick and credible decisions. The amendment would require nominal expense to small businesses.

Economic Impact on Small Businesses

- 1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.**

The Indiana State Department of Health (ISDH) is unable to provide a precise estimate of the number of individuals affected by this rule. The professional licensing agency reports that there are 23,726 active licensed physicians and 1,644 osteopaths for a total of 25,370 in Indiana.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

The proposed rule does require reporting within 72 hours of a laboratory-confirmed influenza death, record keeping of the death, and the addition of nominal administrative costs for physicians and administrators. This amendment does not require any new testing of individuals. Physicians and hospitals are already required to report specific communicable diseases to the local health department or the ISDH. Reporting can be done with an electronic reporting form to simplify data capture and use. The ISDH projects approximately 600 to 700 influenza deaths in Indiana in a typical year. Many of these are not confirmed by laboratory testing and would not be reported. The electronic data reporting system has already been developed and is available for use by physicians, hospital administrators or administrators' representatives at no charge. The ISDH projects completion of the form should require five minutes.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

The rule does not increase the economic impact on small business for complying with the rule.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

There are no requirements or costs imposed on small businesses not expressly required by statutes authorizing ISDH to adopt the rule.

5. Regulatory Flexibility Analysis

Other factors considered:

A. Establishment of less stringent compliance or reporting requirements for small businesses.

The proposed amendment provides the least restrictive measure to monitor influenza deaths. This would be especially important during an influenza pandemic. Pandemic influenza is a very serious public health threat and we need to ensure that we have surveillance methods in place prior to an influenza pandemic. Less stringent requirements would increase the likelihood that our citizens and health care workers would be forced to make decisions based on hear say or inadequate information. In any case, public health measures should be taken based on sound science and credible data.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

In order to protect the health of the citizens of Indiana, a less stringent schedule for compliance is not recommended.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

Physicians and hospital administrators, or administrators' representatives, are requested to use State Form 52576 (02-06), Influenza-Associated Deaths Case Investigation, to report influenza deaths.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

The amendments do not add performance standards that were not already required elsewhere in the rule.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

In order to protect the health of the citizens of Indiana, it is necessary that all affected small businesses comply with the rule.

Conclusion

This rule provides the foundation necessary to determine the true Indiana influenza death burden. Additionally, it has the potential to save Indiana citizens lives by providing much needed epidemiological data as evidence to implement appropriate infection control measures. The current method is inadequate, antiquated, and hinders the ability to be able to make quick and credible decisions. The amendment would require nominal expense to small businesses.

Submitted by,

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